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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,803	12/02/2004	Allan Bernard	016325-013800US	2780

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EXAMINER

JUEDES, AMY E

ART UNIT	PAPER NUMBER
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1644

MAIL DATE	DELIVERY MODE
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06/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/516,803

Applicant(s)

BERNARD ET AL.

Examiner

Amy E. Juedes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Restriction is required under 35 U.S.C. 121 and 372.
2. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
3. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Groups 1-7, claims 1-7, drawn to a method for identifying an agent for treating a diabetic or pre-diabetic individual comprising contact an agent with a polypeptide, wherein groups 1-7 correspond to the following polypeptides:

- Group 1: SEQ ID NO: 2,
- Group 2: SEQ ID NO: 8,
- Group 3: SEQ ID NO: 12,
- Group 4: SEQ ID NO: 16,
- Group 5: SEQ ID NO: 22 or 26,
- Group 6: SEQ ID NO: 28,
- Group 7: SEQ ID NO: 32.

Groups 8-14, claims 8-11, drawn to a method of treating a diabetic animal comprising administering an agent that modulates the expression or activity of a polypeptide, wherein groups 8-14 correspond to agents that modulate the activity of following polypeptides:

- Group 8: SEQ ID NO: 2,
- Group 9: SEQ ID NO: 8,
- Group 10: SEQ ID NO: 12,
- Group 11: SEQ ID NO: 16,
- Group 12: SEQ ID NO: 22 or 26,
- Group 13: SEQ ID NO: 28,
- Group 14: SEQ ID NO: 32.

Groups 15-21, claims 12-18, drawn to a method for introducing an expression cassette into a cell, wherein groups 15-21 correspond to expression cassettes linked to a polynucleotide encoding the following polypeptides:

- Group 15: SEQ ID NO: 2,
- Group 16: SEQ ID NO: 8,
- Group 17: SEQ ID NO: 12,
- Group 18: SEQ ID NO: 16,

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Group 19: SEQ ID NO: 22 or 26,
Group 20: SEQ ID NO: 28,
Group 21: SEQ ID NO: 32.

Groups 22-28, claims 19-21 and 24, drawn to a method of diagnosing an individual who has Type 2 diabetes comprising detecting the level of a polypeptide in a sample, wherein groups 22-28 correspond to the following polypeptides:

Group 22: SEQ ID NO: 2,
Group 23: SEQ ID NO: 8,
Group 24: SEQ ID NO: 12,
Group 25: SEQ ID NO: 16,
Group 26: SEQ ID NO: 22 or 26,
Group 27: SEQ ID NO: 28,
Group 28: SEQ ID NO: 32.

Groups 29-35, claims 19 and 22-24, drawn to a method of diagnosing an individual who has Type 2 diabetes comprising detecting the level of a polynucleotide in a sample, wherein groups 28-35 correspond to polynucleotides encoding the following polypeptides:

Group 29: SEQ ID NO: 2,
Group 30: SEQ ID NO: 8,
Group 31: SEQ ID NO: 12,
Group 32: SEQ ID NO: 16,
Group 33: SEQ ID NO: 22 or 26,
Group 34: SEQ ID NO: 28,
Group 35: SEQ ID NO: 32.

Group 36, claims 25-28, drawn to an isolated nucleic acid encoding a polypeptide of SEQ ID NO: 26, and expression vectors and host cells comprising said nucleic acid.

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicant is further required to elect:

a specific polypeptide or polynucleotide encoding a polypeptide, as appropriate, from the group consisting of SEQ ID NO: 22 or SEQ ID NO: 26 (if group 5, 12, 19, 26, or 33 are elected)

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and list all Claims readable thereon including those subsequently added.

7. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

7. The inventions listed as Groups 1-36 and the species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reason:

The invention of Group 19, the method for introducing an expression cassette into a cell, has no special technical feature that defined the contribution over the prior art of U.S. Patent 5,595,911

The '911 patent teaches a method comprising transfecting cells with an expression vector or a viral vector (i.e. an expression cassette comprising a promoter) comprising a nucleic acid molecule encoding PTPH1 (see column 6-7, in particular). Furthermore, the nucleic acid encoding PTPH1 is a nucleic acid that hybridizes under stringent conditions to a nucleic acid molecule encoding SEQ ID NO: 22 or 26, given the 100% identity over large portions of the nucleic acid sequences (see Fig. 1 in particular).

8. Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

9. Accordingly, Groups 1-36 are not so linked as to form a single general inventive concept and restriction is proper.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the

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product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

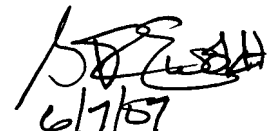
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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6/7/07
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER